UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032

County of Trumbull, Ohio v. Purdue Pharma, L.P., et al.,
Case No. 18-op-45079

"Track 3 Cases"

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

PHARMACY DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS SECOND AMENDED COMPLAINTS

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INTRODUCTORY STATEMENT OF THE ISSUES AND SUMMARY OF ARGUMENT

Plaintiffs Lake County and Trumbull County ("the Counties") seek the common law remedies of damages and abatement for an alleged absolute public nuisance premised on Pharmacy Defendants' having distributed FDA-approved and DEA-regulated opioid medications to their own stores, and then dispensed those medications, based on the professional judgment of their licensed pharmacists, to fill prescriptions written by authorized medical professionals. The Counties' theory is that Ohio common law entitles them to impose liability on Pharmacy Defendants because—they say—Pharmacy Defendants allegedly were required to (1) aggregate and analyze their "extensive data on opioids they distributed and dispensed . . . to help stop diversion," No. 17-md-2804, Doc. 3327 ("Am. Compl.") ¶ 77,[1] and (2) implement certain "policies and procedures" to train their pharmacists and "prevent their stores from facilitating diversion and selling into a black market," *id.* ¶¶ 81–83.

Ohio law requires dismissal of the Counties' common law public nuisance claim. First, Ohio does not permit a common law public nuisance claim based on a pharmacy's alleged failure to detect and prevent the diversion of drugs of abuse. The Ohio legislature has comprehensively regulated the field of controlled substance dispensing and distribution, and has provided specific remedies that conflict with any common law cause of action. A claim like the Counties' may therefore be pursued under Ohio Rev. Code § 4729.35—which permits only *injunctive* relief for a public nuisance action against a pharmacy—or not at all.

Second, the Counties' claim must be dismissed to the extent that it seeks to establish liability based on unlawful conduct with respect to the dispensing of prescription opioid

[1] Because the two Amended Complaints are substantially identical, this Motion cites only to the *Lake County* Amended Complaint for ease of reference.

medications. The Counties' theory ignores a critical distinction between the laws governing the *distribution* of controlled substances, on the one hand, and the *dispensing* of controlled substances, on the other. Although this Court has held that corporations that distribute controlled substances have obligations at the corporate level to maintain certain systems, policies, and procedures to detect "suspicious orders," there is no equivalent corporate-level obligation with respect to dispensing. Instead, the responsibility to guard against invalid prescriptions rests with individual pharmacists, and *only* with individual pharmacists, when they exercise their professional judgment upon being presented with a prescription. And the Counties come nowhere close to adequately alleging that any Pharmacy Defendant's pharmacists engaged in unlawful dispensing in Lake or Trumbull County, or anywhere in Ohio.

Third, the Counties' theory of liability based on Pharmacy Defendants' alleged failure to innovate new ways to identify and prevent diversion does not fit within the elements of an absolute public nuisance claim. The Counties have failed to adequately allege any unlawful or intentional culpable conduct, as required to state a claim for absolute public nuisance under Ohio law. The Counties cannot use the absolute public nuisance doctrine to pursue what is—at bottom—a negligence theory of liability.

Fourth, the Counties' alleged causal chain is—as a matter of law—too attenuated to support liability, as it depends on the intervening misconduct of prescribing doctors and other medical professionals. The Counties' dispensing allegations rest on the idea that pharmacists employed by Pharmacy Defendants filled unlawful prescriptions. But if doctors were writing unlawful prescriptions, they were themselves violating the CSA and its implementing regulations—unlawful conduct that breaks the causal chain as a matter of law. The Counties do not allege that Pharmacy Defendants induced doctors to write the allegedly unlawful

prescriptions that are the crux of their dispensing claims. They allege that ***manufacturers*** engaged in a campaign to encourage doctors to write more opioid prescriptions, but they do not allege that Pharmacy Defendants had anything to do with that messaging to prescribers.

At its essence, the Counties' nuisance action relates to a product (prescription medications) dispensed upon the judgment of pharmacists licensed and governed by comprehensive state and federal controlled substance regimes. So one of two things must be true: Either their nuisance claim is a product liability action or it is an action about the allegedly unlawful way in which that product was sold. If the former, it is covered by the Ohio Product Liability Act, Ohio Rev. Code § 2307.71, uncodified law, which abrogates "all common law product liability causes of action including common law public nuisance causes of action, regardless of how the claim is described, styled, captioned, characterized, or designated." If the latter, it is precluded by Ohio Rev. Code § 4729.35, which permits only injunctive relief for a public nuisance cause of action against a pharmacy based on its allegedly unlawful manner of selling controlled substances. Either way, the Ohio General Assembly has identified the available nuisance remedies. In no event can political subdivisions seek a different remedy on a boundless common law theory.

For these reasons—and all those that Pharmacy Defendants presented in the briefing in the Track One proceedings, incorporated here—the Counties' common law public nuisance claim should be dismissed under Rules 12(b)(1) and 12(b)(6) of the Federal Rules.

BACKGROUND

Plaintiff Lake County filed its initial complaint on December 1, 2017, alleging that opioid manufacturers had engaged in "a sophisticated and highly deceptive and unfair marketing campaign" that successfully "reverse[d] the popular and medical understanding of opioids," with

the result that the "prescribing of opioids to treat chronic pain long-term[] is now commonplace." No. 18-op-45032, Doc. 1-2 ¶ 12. According to the initial complaint, "deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions." *Id.* ¶ 46. Plaintiff Trumbull County filed a largely identical complaint on December 11, 2017. No. 18-op-45079, Doc. 1-2. Both cases were consolidated into this Multidistrict Litigation and were largely stayed pending resolution of other "Track One" bellwether proceedings.

On March 18, 2019, the Counties filed additional short form complaints. *See* No. 18-op-45032, Doc. 16; No. 18-op-45079, Doc. 11. The short form complaints "incorporat[ed] as if fully set forth herein [the Plaintiffs'] own prior pleadings" as well as "common factual allegations" from the Amended Complaint filed in the Track One proceedings. *See* No. 18-op-45032, Doc. 16 at 1. The short form complaints added a number of new defendants, including Pharmacy Defendants. *See id.* at 2. The short form complaints alleged that Pharmacy Defendants failed "to effectively monitor and report suspicious orders of prescription opioids" and "to implement measures to prevent diversion through improper prescriptions." *Id.* ¶ 179. Specifically, the short form complaints alleged that Pharmacy Defendants did not "adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions," did not "adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis," and did not "conduct adequate internal or external audits of their opioid sales." *Id.* ¶¶ 194–97.

On April 16, 2020, after the United States Court of Appeals for the Sixth Circuit granted a Writ of Mandamus striking dispensing-related claims from the Track One proceedings, the

Court announced that it would "select a case for a Track 3 bellwether trial in the Northern District of Ohio, at which will be decided: (1) only public nuisance claims (2) against only the pharmacy defendants [(3)] in their roles as distributors and dispensers." No. 17-md-2804, Doc. 3261 at 2. Over Pharmacy Defendants' objections, *see* No. 17-md-2804, Docs. 3276, 3303, 3304, the Court designated the Counties' cases as Track Three proceedings, *see* No. 17-md-2804, Doc. 3282, and granted the Counties leave to file amended complaints, *see* No. 17-md-2804, Docs. 3294, 3295, 3296, 3314.

The Amended Complaints expressly incorporate the allegations and claims raised both in the initial complaints and in the subsequent short form complaints. *See* Am. Compl. ¶ 1. The Amended Complaints allege that Pharmacy Defendants "failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified." *Id.* ¶ 9. The Counties allege that Pharmacy Defendants had access to "extensive data on opioids they distributed and dispensed" and that this data was "a valuable resource that they could and should have used to help stop diversion." *Id.* ¶ 77. The Counties allege that Pharmacy Defendants "systemically ignored red flags that they were fueling a black market," did not "adequately train their pharmacists and pharmacy technicians," and "failed to put in place effective policies and procedures to prevent their stores from facilitating diversion and selling into a black market." *Id.* ¶¶ 81–83. Based on these allegations, the Counties allege that Pharmacy Defendants created an absolute public nuisance by distributing and dispensing prescription opioids "in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiff's community, flooded Plaintiff's community with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market." *Id.* ¶ 621.

The Court also granted the Counties' Motion to Bifurcate Bellwether Claims, Join Bellwether Cases for Trial, and to Stay Remaining Claims. *See* No. 17-md-2804, Docs. 3297, 3315. The Court ordered that "Plaintiffs' common law public nuisance claims against Chain Pharmacy Defendants shall be separated from Plaintiffs' remaining claims" and that "all Plaintiffs' claims against Chain Pharmacy Defendants other than common law public nuisance and all Plaintiffs' claims against all other Defendants are stayed." No. 17-md-2804, Doc. 3315 at 4. In accordance with this instruction, this Motion to Dismiss addresses the Counties' absolute public nuisance claim; arguments addressing the Counties' other causes of action will be briefed at a later time and are hereby expressly preserved.

LEGAL STANDARDS

Because "standing is an issue of the court's subject matter jurisdiction," a defendant may raise the plaintiff's lack of standing by bringing a motion to dismiss "under Federal Rule of Civil Procedure 12(b)(1)." *Lyshe v. Levy*, 854 F.3d 855, 857 (6th Cir. 2017). On a motion to dismiss under Rule 12(b)(6), a court must dismiss a complaint if the facts alleged, viewed in the light most favorable to the nonmoving party, fail to state a claim for relief that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This pleading standard requires more than the assertion of legal conclusions. *First Am. Title Co. v. Devaugh*, 480 F.3d 438, 444 (6th Cir. 2007). Cursory or conclusory statements are given no weight, and a complaint that raises only the possibility that a defendant acted unlawfully is insufficient as a matter of law. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). A complaint should also be dismissed "when the allegations . . . , however true, could not raise a claim of entitlement to relief." *Twombly*, 550 U.S. at 558.

ARGUMENT

I. Ohio Law Does Not Permit a Common Law Public Nuisance Claim Based on a Pharmacy's Alleged Failure to Detect and Prevent Diversion of Drugs of Abuse.

Section 4729.35 of the Ohio Revised Code allows certain parties to bring a public nuisance action based on the violation of Ohio or federal laws or Board of Pharmacy regulations "controlling the distribution of a drug of abuse." The Counties, however, do not purport to proceed under this statute—presumably because, as this Court has already determined, it permits only *injunctive* relief. No. 17-md-2804, Doc. 1203 at 29–30. The Counties instead purport to bring public nuisance claims under the common law, seeking monetary damages and abatement. But Ohio law does not permit a plaintiff to bring a common law claim where the Ohio legislature has comprehensively regulated the field and provided specific remedies that conflict with the common law cause of action. Accordingly, the Counties can bring their public nuisance claim under the appropriate statute, Ohio Rev. Code § 4729.35, or not at all.[2] The Counties' common law public nuisance claims must therefore be dismissed.

A. The Ohio General Assembly Has Comprehensively Regulated the Dispensing and Distribution of Controlled Substances, Including Mechanisms for the Enforcement of Those Laws.

Ohio law is clear that "[w]here the General Assembly has codified the law on a subject it is the statutory provisions which are to be followed and it is the legislative policy which is to be observed," displacing the common law that preceded the codification. *Bolles v. Toledo Tr. Co.*, 58 N.E.2d 381, 392 (Ohio 1944), *overruled in part on other grounds by Smyth v. Cleveland Tr. Co.*, 179 N.E.2d 60 (Ohio 1961); *see also Alotech, Ltd. v. Huntington Nat'l Bank*, No. 1:13-CV-

[2] This Court already has ruled that Ohio Rev. Code § 4729.35 controls over the more general statute, Ohio Rev. Code § 3767.03, which provides a cause of action for injunction *or* abatement of a public nuisance. *See* Doc. 1203 at 28–31.

01971-DAP, 2014 WL 281973, at *3 (N.D. Ohio Jan. 24, 2014) (same). This rule applies when the legislature has enacted "general and comprehensive legislation, prescribing minutely a course of conduct to be pursued, the parties and things affected, and elaborately describing limitations and exceptions." *Thompson v. Ford*, 128 N.E.2d 111, 115–16 (Ohio 1955) (quoting 3 Sutherland Statutory Construction § 5305 (3d ed.)). Such a complete statutory scheme is "indicative of a legislative intent that the statute should totally supersede and replace the common law dealing with the subject matter." *Id.* Ohio courts have held, for example, that a statute that prescribes in detail how a car's lights must be used when parked "replaces the precautions enjoined by common law" and "absolves one from liability for claimed negligence in failing to display lights." *Id.* at 116. Likewise, Ohio courts have held that the remedies of the Uniform Commercial Code have supplanted common law causes of action. *Amzee Corp. v. Comerica Bank-Midwest*, No. 01AP-465, 2002 WL 1012998, at *9 (Ohio Ct. App. May 21, 2002); *see also Baggott v. Piper Aircraft Corp.*, 101 F. Supp. 2d 556, 561 (S.D. Ohio 1999) (same).

Because the Ohio General Assembly has comprehensively regulated pharmacies' dispensing and distribution of controlled substances and provided specific enforcement mechanisms and remedies for alleged nuisances arising from violations of those regulations, a common law public nuisance claim based on this conduct is not available under Ohio law. General and comprehensive legislation sets out pharmacies' and pharmacists' obligations with respect to guarding against the diversion of controlled substances and provides specific remedies for violations of these obligations. The Counties' own pleadings acknowledge that Ohio regulations specifically address the conduct allegedly underpinning their claims. For example, the Counties invoke state regulations providing that pharmacy "licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion,"

Ohio Admin. Code § 4729-9-05(A);[3] that "a corresponding responsibility" for the proper dispensing of controlled substances "rests with the pharmacist who dispenses the prescription," *id.* § 4729-5-30(A); and that any entity registered as a wholesale distributor "shall . . . design[] and operate[]"a "system . . . to disclose orders for controlled substances and other drugs subject to abuse," *id.* § 4729-9-16(H).[4] *See* Am. Compl. ¶¶ 556, 559–60.

Chapter 4729 of Revised Code Title XLVII, titled "Pharmacists; Dangerous Drugs," regulates in detail all aspects of pharmacists' professional conduct and the dispensing of prescription medications, including opioid medications.[5] Among other things, this Chapter comprehensively addresses the licensing and discipline of pharmacists; defines what constitutes the unlawful practice of pharmacy or the unlawful selling of drugs without an adequate prescription; and sets forth rules on dispensing opioid medications and record-keeping. *See, e.g.*, Ohio Rev. Code §§ 4729.07 (application for licensure; examination); 4729.071 (criminal records

[3] Effective March 1, 2020, this regulation has been repealed. It was replaced with Ohio Admin. Code § 4729:5-3-14, which similarly requires "terminal distributors of dangerous drugs" to "provide effective controls and procedures to . . . [d]eter and detect the theft and diversion of dangerous drugs; and . . . [e]nsure supervision and control of dangerous drugs."

[4] Effective April 30, 2019, this regulation has been repealed. It was replaced with Ohio Admin. Code § 4729:6-5-05, which requires wholesale distributors of controlled substances to "design and operate a system to identify and report suspicious orders by customers for reported drugs." *Id.* § 4729:6-5-05(C). This regulation, along with the other regulations governing registered wholesale distributors, *id.* § 4729:6-5-01 *et seq.*, provides detailed operational and record-keeping requirements designed to prevent theft and diversion.

[5] Chapter 4729 also created the Ohio Board of Pharmacy, which is "the single State agency in Ohio responsible for administering and enforcing laws governing the practice of pharmacy and the legal distribution of drugs"; "is responsible for administering and enforcing the drug laws of Ohio"; licenses pharmacists, pharmacy interns, and distributors; and is "responsible for regulating the legal distribution of dangerous drugs in Ohio and ensuring the quality of all drugs administered, prescribed, dispensed by prescription, or sold over-the-counter." *See* State of Ohio Board of Pharmacy, *About*, www.pharmacy.ohio.gov/About/General.aspx (last visited June 16, 2020); *see also State ex rel. Carlson v. State Bd. of Pharmacy*, No. 18 MA 0006, 2018 WL 3738398, at *1 (Ohio. Ct. App. July 31, 2018) (same).

check); 4729.08 (qualifications); 4729.12 (license effect and renewal); 4729.27 (pharmacy must be conducted by legally licensed pharmacist); 4729.28 (unlawful selling of drugs or practice of pharmacy); 4729.35 (unlawful distribution of drugs of abuse; prosecution); 4729.37 (filling prescriptions; records); 4729.46 (limitations on dispensing opioid analgesics); 4729.44 (dispensation of naloxone by pharmacist or pharmacy intern without a prescription); 4729.77 (terminal distributor pharmacies to submit prescription information); 4729.80 (disclosure of database information; disclosure of requests for database information); 4729.281 (dispensing of drug without written or oral prescription); 4729.292 (annual on-site inspection of opioid treatment program).

In addition to enacting these statutory provisions, the General Assembly has granted the Board of Pharmacy extensive rulemaking authority. *See id.* §§ 4729.24, 4729.26. The Board of Pharmacy, in turn, has enacted highly detailed "rules pertinent to the practice of pharmacy," which cover virtually every aspect of a pharmacist's professional conduct as well as pharmacy operations. *See, e.g.*, Ohio Admin. Code §§ 4729-37 (regulating the drug database OARRS); 4729:9-1-01 *et seq.* (classifying controlled substances and drugs of concern); 4729-5-30 (defining a valid prescription and laying out a pharmacist's corresponding responsibility); 4729:5-3-01 (specifying in detail how a pharmacy may permissibly dispose of controlled substances); 4729:5-3-02 (requiring pharmacies to notify the state board of pharmacy and law enforcement authorities upon discovery of the theft or significant loss of any dangerous drug or controlled substance); 4729:5-3-14 (requiring pharmacies to maintain physical security systems). The Board of Pharmacy has also enacted detailed rules governing the wholesale distribution of controlled substances. *See id.* §§ 4729-9-05 (security requirements); 4729-9-12 (process for

verifying license prior to sale); 4729-9-16 (minimum requirements for wholesalers); 4729:6-1 *et seq.* (current regulations governing wholesale distributors).

In Chapter 4729, the legislature also enacted a comprehensive mechanism for enforcing these rules—including a provision specifically addressing a "public nuisance" due to the unlawful distribution or dispensing of drugs of abuse "by a pharmacist or other person." *See* Ohio Rev. Code § 4729.35. The legislature determined that the primary source of enforcement would be the Board of Pharmacy, which must license every pharmacist, pharmacy, and wholesale distributor in Ohio and has the power to revoke or suspend any such license or take other disciplinary measures in the event of misconduct. Chapter 4729 further provides for the prosecution of those involved in the unlawful distribution or dispensing of drugs of abuse; permits actions for injunctions by the Board of Pharmacy; authorizes the Board of Pharmacy to impose fines for violations of certain provisions; and sets forth criminal penalties for certain violations. *See, e.g.*, Ohio Rev. Code §§ 4729.24 (board powers; subpoenas; rules); 4729.25 (enforcement; investigation); 4729.64 (injunctive proceedings); 4729.96 (discipline for pharmacy technician trainee, registered pharmacy technician, or certified pharmacy technician); 4729.99 (penalties). On top of all this, the General Assembly specified—as this Court has already recognized, No. 17-md-2804, Doc. 1203 at 30—that violations of these provisions could support a statutory public nuisance claim for *injunctive* relief only. *See* Ohio Rev. Code § 4729.35.

B. This Comprehensive Scheme Supersedes Any Common Law Public Nuisance Cause of Action Based on the Dispensing or Distribution of Controlled Substances.

The Ohio statutory and regulatory scheme governing pharmacies' dispensing and distribution of controlled substances, which "prescrib[es] minutely a course of conduct to be pursued," is "indicative of a legislative intent that the statute should totally supersede and replace

the common law dealing with the subject matter." *Thompson*, 128 N.E.2d at 116 (internal quotation marks omitted); *cf. Delaware v. Purdue Pharma L.P.*, No. N18C-01-223, 2019 WL 446382, at *11 (Del. Sup. Ct. Feb. 4, 2019) ("Delaware's comprehensive pharmacy regulatory scheme and enforcement procedures, as well as federal regulations, preempt the claims alleged in the Complaint."). For common law claims to survive, there would have to be "clear legislative intent that the [statute] is merely cumulative to the common law." *Amzee Corp.*, 2002 WL 1012998, at *9. No such legislative intent exists.

To the contrary, the comprehensive statutory scheme is irreconcilable with the common law public nuisance action the Counties advance. Section 4729.35 clearly and directly contradicts the common law. It specifically provides that "[t]he violation by a pharmacist or other person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse" shall "constitute a public nuisance," but that remedies may be pursued only by certain officials (the Attorney General, a county prosecuting attorney, and, of course, the Board of Pharmacy) and must be limited to "an action in the name of the state to enjoin" the violation. The Court has recognized that the common law permits actions to abate or seek damages for a public nuisance under certain circumstances, but that Section 4729.35 does not. *See* No. 17-md-2804, Doc. 1203 at 30 ("[E]ven a statutorily authorized party may only bring an action to enjoin such violations, not one for abatement.").

The Ohio General Assembly clearly intended to provide a comprehensive regulatory and remedial scheme governing pharmacies' dispensing and distribution of controlled substances that, among its varied enforcement mechanisms, limits public nuisance liability to the relief permitted under Section 4729.35. Such circumscribed public nuisance liability for the dispensing or distribution of controlled substances reflects a legislative judgment—like

Congress's judgment in enacting the federal Controlled Substances Act—that balances the competing public health goals of making medications available to patients who need them and controlling against their abuse. *See Gonzalez v. Raich*, 545 U.S. 1, 24 (2005). This statutory scheme excludes the conflicting common-law cause of action advanced by the Counties. *See Peters Family Farm, Inc. v. Sav. Bank*, No. 10CA2, 2011 WL 497476, at *3 (Ohio Ct. App. Jan. 28, 2011) ("When common-law causes of action and statutory law are in conflict, the Supreme Court of Ohio has held [that] statutory provisions are to govern to the exclusion of prior non-statutory law unless there is a clear legislative intention expressed or necessarily implied that the statutory provisions are merely cumulative." (citation and internal quotation marks omitted)).

Ohio law therefore does not permit the Counties' public nuisance claim, which seeks forms of relief beyond what the General Assembly allowed. Much as this Court concluded that the specific provision, Section 4729.35, must control over an irreconcilable general statute, this same provision must prevail over an irreconcilable common law cause of action. *See* No. 17-md-2804, Doc. 1203 at 30 ("[T]he Court concludes . . . that the General Assembly's reference to 'an action . . . to enjoin such person from engaging in such violation' implies the exclusion of other forms of relief." (quoting Ohio Rev. Code § 4729.35)); *id.* at 31 ("[T]he Court . . . rejects the R&R's conclusion that Ohio Rev. Code § 4729.35 does not expressly limit the categories of relief available for a nuisance claim to an injunction.").

Because Ohio law does not permit a common law public nuisance claim based on pharmacies' alleged failure to detect and prevent diversion of prescription opioid medications, the Counties' common law public nuisance claim must be dismissed.

II. The Public Nuisance Claim Based on Dispensing Should Be Dismissed Because the Counties Have Not Identified Any Unlawful Dispensing Conduct.

Even if the Counties' cause of action against Pharmacy Defendants were not barred by Ohio law (it is, *see supra* Part I), the Court must dismiss the Counties' public nuisance claims to the extent that they seek to impose liability based on the dispensing of prescription opioid medications. Am. Compl. ¶ 620. This Court has held, in the Track One proceedings, that corporations that *distribute* controlled substances have obligations at the corporate level to maintain certain systems, policies, and procedures to detect "suspicious orders," *see* No. 17-md-2804, Doc. 2483 at 13–15, but there is no equivalent corporate-level obligation with respect to *dispensing*. Instead, the responsibility to guard against invalid prescriptions rests with individual pharmacists, and *only* with individual pharmacists, who exercise their professional judgment upon being presented with a prescription. The Counties try to blur and ignore this distinction—but they cannot escape it.

Under the CSA's implementing regulations, which the Counties themselves quote, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with *the pharmacist* who fills the prescription." Am. Compl. ¶ 92 (quoting 21 C.F.R. § 1306.04(a)) (emphasis added). The duty to evaluate prescriptions to ensure their legitimacy thus resides not at the corporate level but at the level of individual pharmacists, and it arises when the pharmacist is presented with a prescription. But the Counties have not alleged any facts that even arguably give rise to vicarious liability for any Pharmacy Defendant based on any improper dispensing by any of their pharmacists in Lake or Trumbull County, or anywhere else. That is because, among other reasons, the Counties have failed to identify any prescription that any Pharmacy Defendant's pharmacist purportedly filled in violation of the CSA. Instead, the Counties seek to impose a

corporate-level obligation to aggregate data across an entire retail pharmacy chain and to implement policies and procedures to identify potentially unlawful prescriptions.

In doing so, the Counties attempt to blur the distinction between pharmacists and pharmacies, describing the CSA duties that are owed solely by *pharmacists* as duties owed by *pharmacies*. *See, e.g.*, Am. Compl. ¶ 92. But not only does federal law refrain from obligating anyone other than the individual pharmacist presented with a prescription to assess its validity, Ohio law expressly forbids a pharmacy from doing so. Only a licensed pharmacist—not the non-pharmacist corporate owner of a pharmacy—may engage in the practice of pharmacy. *See* Ohio Rev. Code § 4729.27. And, under Ohio law, the practice of pharmacy includes "[i]nterpreting prescriptions"; "[d]ispensing drugs"; "[p]erforming drug utilization reviews"; "[a]dvising an individual . . . with regard to the individual's drug therapy"; and other "pharmacist care requiring specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences." Ohio Rev. Code § 4729.01(B). Questioning the validity of a prescription requires precisely this sort of specialized knowledge, judgment, and skill, and is a task that Pharmacy Defendants cannot lawfully usurp from their pharmacists.

Elsewhere in the Complaints, the Counties ignore the distinction between pharmacists and pharmacies, inventing corporate-level dispensing duties that do not exist and for which they cite no legal authority (since none exists). *See* Am. Compl. ¶¶ 94, 104, 106–11. Those duties cannot be found in the CSA or its regulations or in the equivalent Ohio law, and would necessarily require pharmacy-operating corporations to make the types of judgments entrusted exclusively to professional pharmacists under federal and state law.

A. The CSA And Its Implementing Regulations Impose Dispensing Obligations on Individual Pharmacists, Not Corporate-Level Duties On Corporations That Operate Pharmacies.

The only sources of dispensing-related obligations identified by the Counties are the federal CSA, its implementing regulations, and Ohio regulations that mirror the federal scheme. Thus, even though the Counties cannot enforce the CSA, *see, e.g.*, *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290–91 (D. Colo. 2016), their dispensing theory hinges entirely on the contours of those CSA "duties" and whether Pharmacy Defendants violated them. Yet the Counties have not identified a single source of federal or Ohio law that required Pharmacy Defendants to do what the Counties say they were required to do: (a) aggregate and analyze their dispensing data at the corporate level, (b) use that analysis to override the professional judgment of individual pharmacists, or (c) train or evaluate their pharmacist employees in any particular way. Nor could they, because no such provisions exist. While the CSA instructs that DEA's registration decisions for *manufacturers* and *distributors* consider their "maintenance of effective controls against diversion of . . . controlled substances," 21 U.S.C. § 823(a)(1), (b)(1), (d)(1), (e)(1), the statute does not list any such factor for *pharmacies*, *id.* § 823(f)(1)-(5). Congress clearly knew how to indicate a requirement to maintain effective controls against diversion—it did so *four times* in § 823 for every other type of registrant. Yet Congress chose not to impose that additional layer of responsibility on pharmacies. Similarly, DEA regulations requiring registrants to "design and operate a system" to identify "suspicious orders of controlled substances," apply to distributors—but not to pharmacies. 21 C.F.R. § 1301.74(a)–(b).[6]

[6] The Counties cite 21 C.F.R. § 1301.71(a), which requires all registrants to provide effective controls to guard against the theft and diversion of controlled substances. But with respect to pharmacies, this regulation only imposes requirements for in-store physical security controls and has never been understood to require a "system" for monitoring prescriptions and disclosing "suspicious orders of controlled substances," *id.* § 1301.74(a)–(b) (applying this "system"

The obligation to evaluate a prescription and guard against dispensing-based diversion resides not at the corporate level but with the individual pharmacist presented with a prescription. The regulation could not be clearer: "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with *the pharmacist who fills the prescription*." *Id.* § 1306.04(a) (emphasis added); *see also* Ohio Admin. Code § 4729-5-21(A) (same); *id.* § 4729-5-30(A) (same). The regulatory text assigns primary responsibility for ensuring the proper prescribing and dispensing of controlled substances to the doctor or other prescriber and a "corresponding" responsibility to the "pharmacist" who fills the prescription. Like Ohio law, DEA regulations define "pharmacist" as a state-licensed professional *individual*, not a pharmacy corporation. 21 C.F.R. § 1300.01; Ohio Admin. Code § 4729:1-1-01(M). The regulation's description of a pharmacist's responsibility as "corresponding" to the responsibility of the "prescribing practitioner" reinforces that the obligation rests with the pharmacist, not the corporate owner. The responsibilities are both *professional* in nature—demanding the exercise of specialized judgment by a professional who has earned the required degree and is trained and licensed in a regulated discipline.

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requirement only to distributors of controlled substances); *see also, e.g.*, *ChipRX, L.L.C., d/b/a City Center Pharmacy*, 82 Fed. Reg. 51,433-02, 51,434 (DEA Nov. 6, 2017) (pharmacy was alleged to have failed to maintain effective controls against diversion and theft where the pharmacist-in-charge was routinely stealing controlled substances to fuel his own addiction and deleting surveillance video footage of his unlawful removal of controlled substances from the pharmacy premises). The same is true of the equivalent Ohio provision. *See* Am. Compl. ¶ 559 (citing Ohio Admin. Code § 4729-9-05(A)). The Ohio regulation provides that, "[i]n evaluating the overall security system of a [pharmacy]," relevant factors that the Ohio Board of Pharmacy may consider include "[t]ype of building construction comprising the facility," "[t]ype of vaults, safes, and secure enclosures or other storage system . . . used," "[t]ype of closures on vaults, safes, and secure enclosures," "[a]dequacy of electronic detection and alarm systems," and "[p]rocedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel." Ohio Admin. Code § 4729-9-05(A); *see also id.* § 4729:5-3-14. None of the relevant factors includes aggregation or analysis of dispensing data, or policies relating to pharmacists' dispensing.

Decades of agency practice confirm that any regulatory obligation to determine whether a prescription was not written for a legitimate medical purpose rests exclusively with the pharmacist presented with that prescription. *See, e.g.*, *Bob's Pharmacy & Diabetic Supplies*, 74 Fed. Reg. 19,599-03, 19,601 (DEA Apr. 29, 2009) ("DEA has long interpreted [21 C.F.R. § 1306.04(a)] 'as prohibiting a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose.'" (quoting *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364-01, 381 (DEA Jan. 2, 2008)); *Edge Pharmacy*, 81 Fed. Reg. 72,092-03, 72,111 (DEA Oct. 19, 2016) ("[T]o prove a violation of the corresponding responsibility, the Government must show that *the pharmacist* acted with the requisite degree of scienter.") (emphasis added).

Although DEA has sometimes referred to the pharmacist's responsibility as the pharmacy's responsibility, *see* Am. Compl. ¶ 93 n.11, that occasional imprecision does not create an independent regulatory responsibility for a pharmacy.[7] In practice, when inquiring into "corresponding responsibility," DEA has always assessed the circumstances from the perspective of the individual pharmacist and asked whether that pharmacist dispensed medications with knowledge that they were not for a legitimate medical purpose. Nor has DEA ever, to Pharmacy Defendants' knowledge, penalized a pharmacy for improper dispensing without determining that a specific pharmacist employed by the pharmacy violated the pharmacist's corresponding responsibility. *See, e.g., Holiday CVS*, 77 Fed. Reg. 62,316-01, 62,317, 62,320–21 (DEA Oct. 12, 2012) (basing the finding that respondent pharmacies violated "their corresponding responsibility under federal law" on the finding that "each Respondent dispensed numerous

[7] DEA has never, to Pharmacy Defendants' knowledge, even accidentally referred to a duty or responsibility of a corporation that operates a chain of pharmacies.

prescriptions when *their pharmacists* either knew or had reason to know that the prescriptions lacked a legitimate medical purpose and were issued outside the usual course of professional practice" (emphasis added)).[8]

All of this illustrates why the Counties' haphazard allegations that Pharmacy Defendants had a corporate-level duty to enact specific systems, policies, or procedures to prevent improper dispensing cannot be reconciled with the sources of law on which the Counties rely. The CSA, its implementing regulations, and the corresponding Ohio statutes and regulations nowhere impose a duty (1) to "analyze [dispensing] data and store level information" for indicators of potential diversion, Am. Compl. ¶ 109; (2) to implement or refrain from implementing particular "policies" for compensating or training their pharmacist employees, *see, e.g.*, *id.* ¶¶ 85, 209, 260–62, 316–17, 377; (3) to provide additional training in dispensing for pharmacists, *id.* ¶ 82; (4) to "use data" to identify doctors writing suspicious volumes of prescriptions or to avoid filling prescriptions, *id.* ¶¶ 211, 289, 388; (5) to conduct specific analyses of prescription sales, *id.* ¶ 149; or (6) to conduct "internal or external reviews" of pharmacy sales, *id.* ¶ 83.

The reason the relevant statutes and regulations do not say any of those things is because the dispensing of controlled substances is and must be an exercise of professional judgment,

[8] To the extent that any DEA opinion has ever suggested that a pharmacy itself has a responsibility—separate from that of its pharmacists—to prevent the diversion of controlled substances through dispensing, such language in an administrative adjudication cannot establish a "rule" that "must . . . be obeyed." *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 (1969) (plurality op.); *see also NLRB v. Fin. Inst. Emps.*, 475 U.S. 192, 202 (1986) (adjudication cannot be used as a vehicle for "unauthorized assumption . . . of major policy decisions properly made by Congress" (internal quotation marks omitted)). Nor could the existence of such a suggestion constitute a reasonable construction of any ambiguous provision of the CSA or its implementing regulations. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019). As demonstrated above, there is no such ambiguity. Of course, even if a "pharmacy" did have such a responsibility, the responsibility would attach at the level of the registrant pharmacy and could not require the aggregation and analysis of data across a pharmacy chain.

prescription by prescription, by a licensed and trained pharmacist. *See* 21 C.F.R. § 1306.04(a); Ohio Admin. Code § 4729-5-21. Even if a Pharmacy Defendant aggregated and analyzed data in all the ways the Counties allege that it should, each of its pharmacists would still be required by law to exercise his or her professional judgment—*i.e.*, his or her "corresponding responsibility"—when filling each opioid prescription for each patient and could not rely on corporate policies or procedures in lieu of that judgment. Lawmakers are free to amend the existing scheme to impose additional controls on how a corporation that operates a chain of pharmacies must analyze its data or evaluate its employees, but nothing now in law imposes those duties.

B. The Counties Cannot Hold Pharmacy Defendants Liable for Improper Dispensing Because They Have Not Identified a Single Instance of Any Pharmacy Defendant's Pharmacist in Lake County or Trumbull County Knowingly Filling a Prescription Written For an Illegitimate Purpose.

The Counties have not adequately pleaded a violation of the duties placed on individual pharmacists by any Pharmacy Defendant's pharmacist working in their jurisdictions. As interpreted by DEA, "to prove a violation of the corresponding responsibility" requires showing not only that a prescription that "lacked a legitimate medical purpose" was dispensed but also that "the pharmacist acted with the requisite degree of scienter." *Superior Pharmacy*, 81 Fed. Reg. 31,310-01, 31,335 (DEA May 18, 2016). The Counties' allegations fall well short of this standard.

The relevant regulations prohibit pharmacists from "knowingly" filling a prescription that was not "issued for a legitimate medical purpose by a [prescriber] acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). This is a high bar, requiring a finding that the pharmacist either (1) filled a prescription despite "actual knowledge that the prescription lacked a legitimate medical purpose" or (2) was "willfully blind (or deliberately ignorant) to the

fact that the prescription lacked a legitimate medical purpose." *Superior Pharmacy*, 81 Fed. Reg. at 31,335; *see also E. Main St. Pharmacy*, 75 Fed. Reg. 66,149-01, 66,150 (DEA Oct. 27, 2010) ("[W]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid actual knowledge of the real purpose of the prescriptions."). "Willful blindness" is a stringent standard that prevents parties from "deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the circumstances." *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011).

The statutory and regulatory context surrounding § 1306.04 confirms this high bar. In addition to defining and assigning the corresponding responsibility to pharmacists, § 1306.04 interprets the CSA's requirement that controlled substances be dispensed only upon a legitimate prescription. *See* 21 U.S.C. § 829. The second sentence of § 1306.04(a) provides that the CSA is violated only if the person filling the prescription *knows* it is illegitimate. *See* 21 C.F.R. § 1306.04(a) ("An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person *knowingly* filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.") (emphasis added); *see also* Ohio Admin. Code § 4729-5-21(A) (same); *id.* § 4729-5-30(A) (same).[9]

[9] This means that, even if pharmacists' CSA duties *did* apply to corporations that operate pharmacies (and they do not), the Counties still have not adequately pleaded a violation. Any such duty would be limited to a duty not to *knowingly* fill a specific prescription written by a practitioner acting outside the usual course of professional practice. *See generally* 21 C.F.R. § 1306.04(a). But the Counties nowhere allege that any Pharmacy Defendant (or any of their employees) *knowingly* filled any specific prescriptions written outside the usual course of professional practice in Lake County or in Trumbull County. Indeed, they do not identify any

The Counties' suggestion that mere negligence or suspicion is sufficient to give rise to pharmacist liability under the CSA, *e.g.*, Am. Compl. ¶¶ 140–41, 202, 209, 263, 287, 292, 313–14, 365, 369, is thus contrary to the language of the regulation. Because the regulation prohibits *knowingly* filling an invalid prescription, it is manifestly not enough to assert that pharmacists may have filled prescriptions despite so-called "red flags." The term "red flags" does not appear in the CSA or its regulations, but is a shorthand used by DEA in certain administrative proceedings for indicia that *might* give a pharmacist reason to *suspect* that a specific prescription was not legitimate. Thus, the fact that a prescription was associated with a "red flag" does not prove that the prescription lacked a legitimate medical purpose. And even "proof that a pharmacist dispensed a controlled substance prescription without resolving a red flag which only created a 'reasonable suspicion' that the prescription lacked a legitimate medical purpose, is not enough to establish that a pharmacist acted with the requisite scienter" to establish a violation of the regulations. *Superior Pharmacy*, 81 Fed. Reg. at 31,335 n.54.

Even assuming, then, that the Counties are correct that corporations that operate pharmacies can be subject to vicarious liability for their pharmacists' CSA violations in some circumstances, Am. Compl. ¶ 61, the Counties never allege that any pharmacist employed by any Pharmacy Defendant in Lake County or Trumbull County—or elsewhere in Ohio—ever knowingly filled an opioid prescription that lacked a legitimate medical purpose. This is fatal to any theory of derivative liability as a matter of both law and logic. A principal cannot be sued for its agent's tort absent allegations sufficient to show that the agent violated a cognizable duty to the plaintiff in the first place. *See Auer v. Paliath*, 17 N.E.3d 561, 564 (Ohio 2014) ("The

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specific prescriptions at all. General allegations about diversion, the ability (or failure) to analyze data, or mere suspicion based on aggregate volume across chain stores simply do not suffice. *See, e.g.*, Am. Compl. ¶¶ 149, 151, 202, 289–90, 320, 330, 365, 368, 388, 409.

respondeat superior doctrine makes an employer or principal vicariously liable for *the torts* of its employees or agents." (emphasis added)); *Nat'l Union Fire Ins. Co. of Pittsburgh, PA v. Wuerth*, 913 N.E.2d 939, 944 (Ohio 2009) ("[A] principal is vicariously liable *only when an agent could be held directly liable*." (emphasis added)).[10] Because the Counties have not done so, the Court should dismiss their claims.

III. The Counties' Challenge to Pharmacy Defendants' Corporate Procedures Does Not Fit Within The Elements Of Ohio's Absolute Public Nuisance Doctrine.

The Court must also dismiss the Counties' public nuisance claims because they do not state a claim under Ohio's absolute public nuisance doctrine. The Counties assert that pharmacy chains have an affirmative obligation to "analyze data relating to drug utilization and prescribing patterns across multiple retail stores" in order to identify unlawful prescriptions, Am. Compl. ¶ 149, and, to that end, were required to "design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations," *id.* ¶ 151. However, the Counties cannot state an absolute nuisance claim by alleging that Pharmacy Defendants should have taken greater precautions when engaging in otherwise lawful conduct.

The Counties' claims fundamentally sound in negligence and—as a result—are antithetical to the absolute nuisance doctrine. In Ohio, a public nuisance can be either absolute or qualified: A qualified nuisance requires proof of negligence, whereas an absolute nuisance requires proof of either culpable unlawful conduct or intentional, culpable conduct. *See, e.g.*, *Barnett v. Carr*, No. CA2000-11-219, 2001 WL 1078980, at *10–11 (Ohio Ct. App. Sept. 17,

[10] It is not remotely enough for the Counties to rely on allegations about enforcement actions involving Pharmacy Defendants' pharmacists outside of Ohio. *See* Am. Compl. ¶¶ 380, 499, 504, 508, 509, 515, 519–20, 532. Even if these allegations supported an inference that a Pharmacy Defendant's pharmacist *knowingly* filled an illegitimate opioid prescription, none has any alleged connection to the Counties and their claimed injuries.

2001).[11] Here, the Counties eschew any qualified nuisance claim—instead raising a claim under the absolute nuisance doctrine. *See* Am. Compl. ¶ 620. Having so framed their case, the Counties cannot proceed by arguing that Pharmacy Defendants negligently failed to take reasonable precautions; the Counties must prove that the conduct at issue entitles them to relief even without proof of negligence. Yet the Counties seek to proceed with what—at bottom—is a negligence theory: They allege that Pharmacy Defendants did not "design and implement systems" that would prevent their conduct from causing unnecessary harm. *Id.* ¶ 151. Allowing that claim to proceed under the guise of absolute nuisance doctrine would inappropriately excuse the Counties from the obligation to prove all the elements of negligence to prevail on a qualified nuisance claim.

The Counties do not adequately allege either unlawful or intentional, culpable conduct, as required to state an absolute public nuisance claim. As explained above, neither state nor federal law provides any support for the Counties' contention that Pharmacy Defendants were required to design and implement additional "systems" to mine prescription data across multiple pharmacy locations within a chain or adopt other corporate-level policies and procedures in order to identify unlawful prescriptions. *See supra* Part II.A. Moreover, the Counties' claim that Pharmacy Defendants were obligated to implement such systems is not a claim for intentional

[11] An absolute nuisance may also arise where a defendant engages in conduct "resulting in accidental harm, for which, because of the hazards involved, absolute liability attaches notwithstanding the absence of fault." *Barnett*, 2001 WL 1078980, at *11. The Counties have not invoked that doctrine here. *See* Am. Compl. ¶ 620 (alleging that "[t]he public nuisance is an *absolute* public nuisance because Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes which established specific legal requirements for the protection of others"). There is a good reason why they have not: Pharmacy dispensing is lawful, regulated, and licensed conduct that provides no basis for imposition of strict liability. *See State ex rel. Schoener v. Hamilton Cty. Bd. of Commrs.*, 619 N.E.2d 2, 6 (Ohio Ct. App. 1992).

culpable conduct: While Pharmacy Defendants' pharmacists no doubt acted intentionally when they dispensed medications to fill prescriptions, that conduct in itself was entirely lawful and is not the type of intentional culpable conduct that could support an absolute public nuisance claim. *See Schoener*, 619 N.E.2d at 5–6 (rejecting absolute nuisance claim based on licensed and regulated conduct). The Counties instead allege that Pharmacy Defendants' otherwise lawful conduct became unlawful because they failed to implement certain policies and procedures that the Counties imagine could have prevented harm. The suggestion that Pharmacy Defendants should have innovated new ways to identify and prevent diversion does not state a claim for intentional culpable misconduct under Ohio's public nuisance doctrine.

The same is true of the Counties' claim that Pharmacy Defendants adopted "performance metrics and prescription quotas" that created incentives for pharmacists to fill prescriptions too quickly. Am. Compl. ¶ 413; *see also id.* ¶¶ 414–33. Even if that were true (it is not), the Counties do not point to any law or regulation that would make it unlawful for a pharmacy chain to adopt policies that use performance metrics in evaluating employees. The Counties also do not allege any facts even remotely suggesting that any Pharmacy Defendant adopted such policies with an intent to cause the asserted harms that the Counties have sued to address. *See Nottke v. Norfolk S. Ry. Co.*, 264 F. Supp. 3d 859, 863 (N.D. Ohio 2017) (absolute nuisance plaintiff must show that defendant "intended to bring about the conditions which are in fact found to be a nuisance" (internal quotation marks omitted)). To the contrary, the Counties expressly allege that the alleged policies were motivated by a different intent altogether—a desire to increase profitability. *See, e.g.*, Am. Compl. ¶ 425 (accusing Pharmacy Defendants of a "focus on profits"). This, too, is ultimately a negligence claim, and, as such, the Counties cannot pursue it under the guise of the absolute public nuisance doctrine.

Lastly, the Counties cannot avoid this outcome by attempting to frame this as a challenge to Pharmacy Defendants' participation in trade groups that lobbied against additional regulation of the opioid supply chain. *See* Am. Compl. ¶¶ 434–47. No matter what the Counties think of that alleged lobbying activity as a policy matter, the First Amendment bars any attempt to impose liability based on it. *See, e.g.*, *In re Asbestos Sch. Litig.*, 46 F.3d 1284, 1294 (3d Cir. 1994) (explaining that "[j]oining organizations that participate in public debate, making contributions to them, and attending their meetings are activities that enjoy substantial First Amendment protection"). If the Counties disagree with laws or regulations that were implemented as a result of these alleged lobbying activities, they should direct their complaints to the government officials who enacted those laws and regulations, or challenge them in court. The Counties cannot treat participation in the democratic process as a public nuisance simply because they are unhappy with the result.

IV. The Role Of Doctors As Learned Intermediaries Bars Any Finding Of Proximate Causation As A Matter Of Law.

Finally, the Counties' own allegations, which depend on the intervening conduct of prescribing doctors and other medical professionals, *see, e.g.*, Am. Compl. ¶¶ 5, 13, 149, preclude any finding that Pharmacy Defendants' conduct dispensing prescription medications proximately caused their asserted injuries. Under the learned intermediary doctrine, the intervening conduct of prescribing medical professionals breaks the causal chain as a matter of law.

The Counties' dispensing allegations rest on an alleged causal chain that runs directly through the conduct of prescribing doctors and other medical professionals. The Counties assert that Pharmacy Defendants did not train pharmacists to conduct "a proper inquiry into whether a prescription is legitimate" or "conduct adequate internal or external reviews of their opioid sales

to identify patterns regarding prescriptions that should not have been filled." Am. Compl. ¶¶ 82–83. If doctors were writing prescriptions other than for a "legitimate medical purpose," however, those doctors were themselves violating the CSA and its implementing regulations. 21 C.F.R. § 1306.04(a). While pharmacists bear a "corresponding responsibility" when filling a prescription, *see supra* pp. 17, 20—a responsibility that the Counties do not allege that any Pharmacy Defendant's pharmacist violated within their jurisdictions—the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner." 21 C.F.R. § 1306.04(a). As courts in Ohio have long recognized, the "patient is expected to place primary reliance upon the physician's judgment," *Seley v. G. D. Searle & Co.*, 423 N.E.2d 831, 840 (Ohio 1981), and others in the supply chain may "reasonably assume that the physician will exercise his informed judgment in the patient's best interests," *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 878–79 (Ohio 1991); *see also Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 596 (S.D. Ohio 2003) (dismissing claim against opioid manufacturers based on doctors' role as learned intermediaries).

The unlawful conduct of the prescribing physicians breaks the causal chain as a matter of law. Unlawful conduct provides "a sufficient intervening or superseding cause to break the chain of causation" even if that unlawful conduct could have been foreseen—and even if the defendant in some sense facilitated that unlawful conduct—so long as the defendant did not "induce[ ] negligent or reckless behavior" on the part of the unlawful actor. *Pendrey v. Barnes*, 479 N.E.2d 283, 284 (Ohio 1985). That rule squarely applies here, as the Counties do not allege that any Pharmacy Defendant in any way induced prescribers to write the allegedly unlawful prescriptions that are the focus of their dispensing claims. To be sure, the Counties allege that *manufacturers* engaged in a campaign to encourage doctors to write more opioid prescriptions.

The Counties do not (and cannot) allege, however, that any Pharmacy Defendant played a knowing role in this campaign.[12] To the contrary, the Counties acknowledge that pharmacists were the targets of some of the very same marketing messages that were directed at doctors and other medical professionals—for instance, through continuing education events, *see, e.g.*, Am. Compl. ¶¶ 457–58, 472, 478. Under the learned intermediary doctrine, Pharmacy Defendants appropriately relied on prescribing medical professionals to evaluate manufacturers' marketing and set the standard of care.

Moreover, even if foreseeability were the appropriate test, the learned intermediary doctrine still would bar liability as a matter of law. The Counties do not just allege isolated misconduct by a few prescribing doctors; after all, any such isolated misconduct would be insufficient to cause the "significant interference with rights common to the general public" that the Counties allege. Am. Compl. ¶ 625. Instead, the Counties allege that doctors engaged in "widespread" inappropriate prescribing as a result of manufacturers' efforts directed to changing prescribers' standard of care. *See, e.g.*, *id.* ¶ 637; *see also* No. 18-op-45032, Doc. 1-2 ¶ 12 (alleging that manufacturers "reversed the popular and medical understanding of opioids"). But Pharmacy Defendants were not required—or equipped—to second-guess the collective judgment of the medical profession in that regard. To the contrary, Pharmacy Defendants were entitled to "reasonably assume" that doctors would exercise "informed judgment" to adopt an appropriate standard of care. *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d at 878–79. Pharmacy

[12] The Counties allege that certain Pharmacy Defendants engaged in marketing behavior by passing on rebates and participating in other pricing incentives offered by manufacturers and by passing on information to pharmacists and/or patients. *See, e.g.*, Am. Compl. ¶ 465. These allegations, however, have nothing to do with influencing the standard of care for prescribing physicians.

Defendants are not doctors and—as a matter of law—could not foresee harms that even the medical profession did not anticipate.

This Court's decisions in the Track One cases are not to the contrary. When the Track One Defendants raised the learned intermediary doctrine in their motions to dismiss, the Special Master's Report and Recommendation concluded that the doctrine was inapplicable to the *Manufacturer* Defendants because they had allegedly tainted doctors' prescribing through their deceptive marketing. No. 17-md-2804, Doc. 1025 at 30. As noted above, though, Pharmacy Defendants are not alleged to be the perpetrators of this marketing scheme against doctors. As to the "supply-side allegations," the Report and Recommendation also found the doctrine inapplicable to *distributors* on the ground that they had "an obligation to report suspicious orders" independent of whether any particular prescription should or should not have been filled; at that wholesale distribution level, the Special Master concluded, distributors had "no cogent rationale explaining how the prescribing physicians would be an intervening cause." *Id.* That rationale illustrates why the learned intermediary doctrine bars the Counties' dispensing claims: Those claims are based entirely on Pharmacy Defendants' conduct filling prescriptions written by doctors and other medical professionals, and thus the causal chain necessarily runs directly through the independent conduct of those prescribers.[13]

[13] The Court's decision in *Muscogee (Creek) Nation* is also not to the contrary. In that case, the Court did not categorically reject the argument that the learned intermediary doctrine may, as a matter of law, bar dispensing claims but held only that the pharmacies had not adequately "explain[ed] how the Nation's alleged causal chain differs from that of the *Track One* Plaintiffs[]," which asserted claims only against manufacturers and wholesale distributors. No. 17-md-2804, Doc. 1680 at 9.

V. The Court Must Dismiss the Counties' Claims For Additional Reasons Previously Adjudicated In The Track One Cases.

To avoid redundant briefing, Pharmacy Defendants have not briefed arguments here that this Court already rejected in the Track One proceedings. Pharmacy Defendants respectfully submit that this Court erred in rejecting those arguments, however, and hereby incorporate the Track One briefing to preserve those arguments for appellate review. *See* No. 17-md-2804, Doc. 497 (Pharmacy Defendants' motion to dismiss); Doc. 491 (Distributor Defendants' motion to dismiss); Doc. 1874 (motion for summary judgment on statute of limitations); Doc. 1883 (motion for summary judgment on preemption); Doc. 1885 (motion for summary judgment on causation). Without limitation, arguments incorporated and preserved include:

- The Counties lack Article III standing to sue for indirect injuries incurred in the first instance by third parties not before the Court. *See Coyne v. Am. Tobacco Co.*, 183 F.3d 488 (6th Cir. 1999); *see also* No. 17-md-2804, Doc. 497-1 at 4–7.
- The derivative nature of the Counties' injuries also defeats any finding of proximate cause. *See City of Cleveland v. Ameriquest Mortg. Secs., Inc.*, 621 F. Supp. 2d 513, 535–36 (N.D. Ohio 2009); *see also* No. 17-md-2804, Doc. 497-1 at 16; Doc. 491-1 at 45–49.
- The Counties cannot establish proximate cause because liability is cut off by numerous intervening factors, including the intervening unlawful conduct of individuals who abuse prescription opioid medications. *See Ameriquest*, 621 F. Supp. 2d at 516, 533–34; *see also* No. 17-md-2804, Doc. 497-1 at 14–16.
- The Counties' claims are barred by the economic loss doctrine. *See City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 477 (6th Cir. 2017); *see also* No. 17-md-2804, Doc. 491-1 at 43–44.
- The Counties' claims are barred by the statewide concern doctrine. *See Am. Fin. Servs. Ass'n v. City of Cleveland*, 858 N.E.2d 776, 781 (Ohio 2006); *see also* No. 17-md-2804, Doc. 491-1 at 44–45.
- The Counties' absolute public nuisance cause of action is abrogated by the Ohio Product Liability Act. *See* Ohio Rev. Code § 2307.71(A)(13); *see also* No. 17-md-2804, Doc. 497-1 at 8; Doc. 491-1 at 22–26.
- The Counties' claim for an absolute public nuisance fails because they do not allege interference with a public right. *See Kramer v. Angel's Path, L.C.*, 882 N.E. 2d 46, 52 (Ohio Ct. App. 2007); *see also* No. 17-md-2804, Doc. 497-1 at 20; Doc. 491-1 at 26–29.

- The Counties' claim for an absolute public nuisance fails because it is directed at authorized and regulated activities. *See Brown v. Scioto Cty. Bd. of Commrs.*, 622 N.E.2d 1153, 1158–60 (Ohio Ct. App. 1993); *see also* No. 17-md-2804, Doc. 497-1 at 20; Doc. 491-1 at 29–30.

- The Counties' claims are preempted by federal law, including provisions of the CSA that give DEA discretion to enforce the dispensing and distribution-related provisions of that law. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *see also* No. 17-md-2804, Doc. 1883-1.

- The Counties' absolute public nuisance claim is barred by the applicable statute of limitations. *See* No. 17-md-2804, Doc. 1874.

In addition, as noted above, this motion is limited to the common law public nuisance claims that are at issue in these Track 3 proceedings and does not address the additional remaining claims that this Court has ordered stayed. *See* No. 17-md-2804, Doc. 3315 at 4. Pharmacy Defendants expressly reserve all challenges to those additional causes of action, which will be briefed, if necessary, at a later time to be set by the Court.

CONCLUSION

For the foregoing reasons, the Counties' public nuisance claims against Pharmacy Defendants should be dismissed with prejudice.

Dated: June 16, 2020

Respectfully submitted,

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[14] CVS Health Corporation separately has filed a motion to dismiss for lack of personal jurisdiction. It joins this motion subject to and without waiving its jurisdictional position.

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record on June 16, 2020.

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